attachment 1 K955420

510(k) Summary of Safety and Effectiveness for Pathromtin SL

1. Manufacturer Name, Address, phone number, contact name and date of preparation:

Manufacturer
Behringwerke AG
Postfach 1140
35001 Marburg
Germany

APR 19 1996

Distributor:
Behring Diagnostics Inc.,
151 University Avenue
Westwood, MA 02090
617-320-3153
Contact name: Nancy M Johansen

date of preparation: November 27, 1995

2. Device Name/Classification:

Reagents for use in the determination of activated partial thromboplastin time/Class II (864-7925)

3. Identification of the legally marketed device to which the submitter claims equivalence.

Dade® Actin® FS Activated PTT Reagent

4. Proposed Device Description:

Pathromtin SL is a reagent consisting of a phospholipid (vegetable) and a surface activator (silicon dioxide particles) used to activate the factors of the intrinsic coagulation system.

5. Proposed Device Intended Use:

Pathromtin SL is a reagent for the determination of the activated partial thromboplastin time in human plasma.

6. Medical device to which equivalence is claimed and comparison information:

Pathromtin SL is substantially equivalent in intended use and results obtained to the Actin® FS aPTT reagent. Both assays contain phospholipids (phosphatides) and an activator to initiate the intrinsic coagulation system. Both depend on the addition of calcium chloride to complete the coagulation process.

7. Proposed Device Performance characteristics:

Correlation:
Results of comparative studies using the Pathromtin SL reagent and the Actin® FS aPTT reagent with 212 plasma samples gave a correlation coefficient of 0.96 and a y-intercept of 2.1, and a slope of 0.99.

Precision:
Precision studies were run over a 5 day period, twice per day, to total n=40. Intra-assay precision was calculated from the n=4 precision values over the 5 days. Intra-assay precision ranges from 0.3-2.5 %CV, while the inter-assay precision ranged from 0.7-3.3 %CV.